



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 31, 2015

GE Healthcare Finland Oy
% Joel Kent
Regulatory Affairs Manager
GE Healthcare
86 Pilgrim Road
Needham, Massachusetts 02492

Re: K143676
Trade/Device Name: B40i Patient Monitor
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm).
Regulatory Class: Class II
Product Code: MHX, BZQ, CBQ, CBR, CBS, CCK, CCL, DSK, DQA, DRT, DSB, DXN, FLL, GWQ, NHO, NHQ, NHP
Dated: June 17, 2015
Received: June 23, 2015

Dear Joel Kent,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K143676

Device Name: **B40i**

Indications for use:

The B40i is a portable multi-parameter unit to be used for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adult, pediatric, and neonatal patients in a hospital environment and during intra-hospital transport. The B40i is intended for use under the direct supervision of a licensed health care practitioner.

The B40i is not intended for use during MRI.

The B40i can be a stand-alone monitor or interfaced to other devices via a network. The B40i monitors and displays: ECG (including ST segment, arrhythmia detection), invasive blood pressure, heart/pulse rate, oscillometric non-invasive blood pressure (systolic, diastolic and mean arterial pressure), functional oxygen saturation (SpO2) and pulse rate via continuous monitoring (including monitoring during conditions of clinical patient motion or low perfusion), temperature with a reusable or disposable electronic thermometer for continual monitoring Esophageal/Nasopharyngeal/Tympanic/Rectal/Bladder/Axillary/Skin/Airway/Room/Myocardial/Core/Surface temperature, impedance respiration, respiration rate, airway gases (CO2, O2, N2O, anesthetic agents, anesthetic agent identification and respiratory rate) and Entropy.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

In accordance with 21 CFR 807.92(c) the following summary of information is provided:

Owner/Contact/Date
(807.92(a)(1)):

Date: 19 December 2014

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Device names (807.92(a)(2)):

Trade Name: B40i
Common/Usual Name: Multi-parameter patient monitor

Classification Names: 21 CFR 870.1025 Arrhythmia detector and alarm (including ST-segment measurement and alarm)

Classification Product Code: MHX

Subsequent Product Codes BZQ CBQ CBR CBS CCK
CCL DQA DRT DSB DSK DXN
FLL GWQ NHO NHP NHQ

Predicate Device(s)
(807.92(a)(3)): K133576 Monitor B40
K071073 Patient Data Module

Device Description
(807.92(a)(4)): The proposed monitor B40i is a multi-parameter patient monitor that is developed based on the predicate Monitor B40 (K133576) platform. The proposed monitor B40i provides support for optional modules (E-Entropy module (K061907) and CARESCAPE Respiratory modules (E-sCO and E-sCAiO) (K123195). The proposed monitor B40i is also compatible with CARESCAPE Respiratory modules (E-sCOV and E-sCAiOV) (K123195) but with disabled spirometry function. The proposed monitor B40i supports Airway Gas Option (N-CAiO). The proposed monitor B40i expands the impedance respiration parameter feature to cover the neonatal patient population compared to the predicate Monitor B40 (K133576). This parameter feature patient population extension to cover neonatal patient population uses Patient Data Module as predicate (K071073), which impedance respiration implementation especially concerning the algorithm used is based on the predicate Aware Transport (K042642). The proposed monitor B40i utilizes 12 inch LCD display panel and LED backlight with an integrated keypad and a pre-configuration patient parameter measurement module. The proposed monitor B40i interfaces with the optional E-MiniC (K052582) and Thermal Recorder with an extension rack. As with the predicate Monitor B40, the proposed monitor B40i includes features and subsystems that are optional or configurable. The proposed monitor B40i interfaces to a variety of existing central station systems via a cabled network interface. As with the predicate Monitor B40, the proposed monitor B40i has a mounting plate on the bottom of the monitor. The monitor can be mounted in a variety of ways (e.g. shelf, countertop, table, wall, pole, or head/foot board) using existing mounting accessories.

Intended Use (807.92(a)(5)): The B40i is a portable multi-parameter unit to be used for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adult, pediatric, and neonatal patients in a hospital environment and during intra-hospital transport.

The B40i is intended for use under the direct supervision of a licensed health care practitioner.

The B40i is not intended for use during MRI.

The B40i can be a stand-alone monitor or interfaced to other devices via a network.

The B40i monitors and displays:

ECG (including ST segment, arrhythmia detection), invasive blood pressure, heart/pulse rate, oscillometric non-invasive blood pressure (systolic, diastolic and mean arterial pressure), functional oxygen saturation (SpO2) and pulse rate via continuous monitoring (including monitoring during conditions of clinical patient motion or low perfusion), temperature with a reusable or disposable electronic thermometer for continual monitoring.

Esophageal/Nasopharyngeal/Tympanic/Rectal/Bladder/Axillary/Skin/Airway/Room/Myocardial/Core/Surface temperature, impedance respiration, respiration rate, airway gases (CO2, O2, N2O, anesthetic agents, anesthetic agent identification and respiratory rate) and Entropy.

Technology (807.92(a)(6)): The proposed monitor B40i is a modified system based on the predicate Monitor B40 (K133576). In addition to the labeling differences with the predicate Monitor B40 (K133576), the proposed monitor B40i also expands the impedance respiration parameter feature to cover the neonatal patient population compared to the predicate Monitor B40 (K133576). Patient Data Module (K071073) is the predicate, which impedance respiration implementation especially concerning the algorithm used is based on the predicate Aware Transport (K042642). The fundamental technology of the proposed monitor B40i is the same as the predicate devices. The proposed monitor B40i is as safe and effective as the predicate devices as summarized in the comparison table below.

Feature/Function	Current Device/System the legally marketed predicate Monitor B40V2.1 (K133576)	Proposed Device/System Name proposed Monitor B40i	Change Explanation/Notes
Intended Use description to include:			
Claims/ features	<p>The Monitor B40 is a portable multi-parameter unit to be used for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adult, pediatric, and neonatal patients in a hospital environment and during intra-hospital transport.</p> <p>The Monitor B40 is intended for use under the direct supervision of a licensed health care practitioner.</p> <p>The Monitor B40 is not intended for use during MRI.</p> <p>The Monitor B40 can be a stand-alone monitor or interfaced to other devices via a network.</p> <p>The Monitor B40 monitors and displays: ECG (including ST segment, arrhythmia detection), invasive blood pressure, heart/pulse rate, oscillometric non-invasive blood pressure (systolic, diastolic and mean arterial pressure), functional oxygen saturation (SpO2) and pulse rate via continuous monitoring (including monitoring during conditions of clinical patient motion or low perfusion), temperature with a reusable or disposable electronic thermometer for continual monitoring.</p> <p>Esophageal/Nasopharyngeal/Tympanic/Rectal/Bladder/Axillary/Skin/Airway/Room/Myocardial/Core/Surface temperature, impedance respiration, respiration rate, airway gases (CO2, O2, N2O, anesthetic agents, anesthetic agent identification and respiratory rate) and Entropy.</p>	<p>The B40i is a portable multi-parameter unit to be used for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adult, pediatric, and neonatal patients in a hospital environment and during intra-hospital transport.</p> <p>The B40i is intended for use under the direct supervision of a licensed health care practitioner.</p> <p>The B40i is not intended for use during MRI.</p> <p>The B40i can be a stand-alone monitor or interfaced to other devices via a network.</p> <p>The B40i monitors and displays: ECG (including ST segment, arrhythmia detection), invasive blood pressure, heart/pulse rate, oscillometric non-invasive blood pressure (systolic, diastolic and mean arterial pressure), functional oxygen saturation (SpO2) and pulse rate via continuous monitoring (including monitoring during conditions of clinical patient motion or low perfusion), temperature with a reusable or disposable electronic thermometer for continual monitoring Esophageal/Nasopharyngeal/Tympanic/Rectal/Bladder/Axillary/Skin/Airway/Room/Myocardial/Core/Surface temperature, impedance respiration, respiration rate, airway gases (CO2, O2, N2O, anesthetic agents, anesthetic agent identification and respiratory rate) and Entropy.</p>	Identical (only the name of the monitor is different)
Patient Population	Adult, pediatric and neonate	Adult, pediatric and neonate	Identical
Environment of Use	hospital environment and during intra-hospital transport	hospital environment and during intra-hospital transport	Identical

Hardware:			
Software Media	Embedded	Embedded	Identical
Battery Type	Lithium-Ion	Lithium-Ion	Identical
Battery run in time	>=2:15 typical monitor configuration: - ECG, NIBP cycle time 5min, SpO2, 2x INVP, 2x Temp and continuous CO2 use - Ambient temperature 25 °C - Display brightness 70%	>=2:15 typical monitor configuration: - ECG, NIBP cycle time 5min, SpO2, 2x INVP, 2x Temp and continuous CO2 use - Ambient temperature 25 °C - Display brightness 70%	Identical
Operating Systems Infrastructure Software:			
Operating System	Linux	Linux	Identical
Networking			
Networking Interface	LAN	LAN	Identical
User Interface			
Front Key Pad	18 hard keys with Trim Knob, and 1 power On/Standby	18 hard keys with Trim Knob, and 1 power On/Standby	Identical
Display:			
Size	12.1-inch	12.1-inch	Identical
Types	TFT LCD	TFT LCD	Identical
Number of Waveform traces	Up to 6	Up to 6	Identical
Alarms:			
Classification	Three levels - Red, Yellow, Cyan	Three levels - Red, Yellow, Cyan	Identical
Notification	Audible and visual	Audible and visual	Identical
Trending:			
Types of trend data	Graphic, numeric data	Graphic, numeric data	Identical
Storage	Up to 72 hours	Up to 72 hours	Identical
Snapshots:			
Snapshots	A snapshot is a frozen frame of preconfigured waveforms or trends saved in the monitor memory of time. Snapshots can contain waveform clips and graphic trends.	A snapshot is a frozen frame of preconfigured waveforms or trends saved in the monitor memory of time. Snapshots can contain waveform clips and graphic trends.	Identical
Printing:			
Printers Supported	Local Thermal Array Recorder, Network laser printer, Strip chart recorder at the Central Station.	Local Thermal Array Recorder, Network laser printer, Strip chart recorder at the Central Station.	Identical
Monitored Parameter: ECG			

Measurement technique	Body surface electrical potential	Body surface electrical potential	Identical
Leads Available	3-leads, 5-leads	3-leads, 5-leads	Identical
Severe arrhythmia analysis	Asystole Bradycardia Tachycardia Ventricular fibrillation Ventricular tachycardia	Asystole Bradycardia Tachycardia Ventricular fibrillation Ventricular tachycardia	Identical
Arrhythmia algorithm	EKPRO V12 Fulfil AAMI EC57-1998 standard	EKPRO V12 Fulfil AAMI EC57-1998 standard	Identical
Monitored Parameter: SpO2			
Measurement Technique	GE SpO2 Nellcor OxiMax SpO2 (Nell1-S OEM board) Masimo SET Radical SpO2 (MS-2011 OEM board)	GE SpO2 Nellcor OxiMax SpO2 (Nell1-S OEM board) Masimo SET Radical SpO2 (MS-2011 OEM board)	Identical
Measurement Range	GE: 1 to 100% Masimo: 1 to 100% Nellcor: 1 to 100%	GE: 1 to 100% Masimo: 1 to 100% Nellcor: 1 to 100%	Identical
Accuracy	GE TruSight SpO2: Adult/Pediatric: Without motion: 70 to 100% ± 2 digits (± 3 digits with ear sensor) With motion: 70 to 100% ± 3 digits Low perfusion : 70 to 100% ± 3 digits 1 to 69%: unspecified Neonatal: without motion: 100 to 70% ± 3 digits with motion: 100 to 70% ± 3 digits 1 to 69%: unspecified Nellcor: Adult: 70 to 100% ± 2 digits Neonate: 70 to 100% ± 3 digits Low Perfusion: 70 to 100% ± 2 digits Masimo: Without Motion - Adult/Pediatric: 70 to 100% ± 2 digits Without Motion – Neonate: 70 to 100% ± 3 digits With Motion - Adult/Pediatric/Neonate: 70 to 100% ± 3 digits Low Perfusion 70 to 100% ± 2 digits 0 to 69% unspecified	GE TruSight SpO2: Adult/Pediatric: Without motion: 70 to 100% ± 2 digits (± 3 digits with ear sensor) With motion: 70 to 100% ± 3 digits Low perfusion : 70 to 100% ± 3 digits 1 to 69%: unspecified Neonatal: without motion: 100 to 70% ± 3 digits with motion: 100 to 70% ± 3 digits 1 to 69%: unspecified Nellcor: Adult: 70 to 100% ± 2 digits Neonate: 70 to 100% ± 3 digits Low Perfusion: 70 to 100% ± 2 digits Masimo: Without Motion - Adult/Pediatric: 70 to 100% ± 2 digits Without Motion – Neonate: 70 to 100% ± 3 digits With Motion - Adult/Pediatric/Neonate: 70 to 100% ± 3 digits Low Perfusion 70 to 100% ± 2 digits 0 to 69% unspecified	Identical

Pulse Rate Detection	GE Trusingal SpO2 : 30- 250 bpm Without motion: 30- 250 bpm \pm 2 bpm (Adult/Pediatric/Neonatal) With motion: 30- 250 bpm \pm 3 bpm (Adult/Pediatric/Neonatal) Low Perfusion: \pm 5 bpm (Adult/Pediatric) Nellcor: 20 to 250 beats/min \pm 3 digits Low Perfusion 20 to 250 beats/min \pm 3 digits Masimo Without Motion 25 to 240 beats/min \pm 3 digits, With Motion normal physiologic range 25 to 240 beats/min \pm 5 digits	GE Trusingal SpO2 : 30- 250 bpm Without motion: 30- 250 bpm \pm 2 bpm (Adult/Pediatric/Neonatal) With motion: 30- 250 bpm \pm 3 bpm (Adult/Pediatric/Neonatal) Low Perfusion: \pm 5 bpm (Adult/Pediatric) Nellcor: 20 to 250 beats/min \pm 3 digits Low Perfusion 20 to 250 beats/min \pm 3 digits Masimo Without Motion 25 to 240 beats/min \pm 3 digits, With Motion normal physiologic range 25 to 240 beats/min \pm 5 digits	Identical
Monitored Parameter: Invasive Blood Pressure			
Measurement technique	Bridge type defibrillator proof transducers	Bridge type defibrillator proof transducers	Identical
Measurement range	-40 ... 320mmHg	-40 ... 320mmHg	Identical
Accuracy of systolic, diastolic, and mean pressures	\pm 5% or \pm 2mmHg (whichever is greater)	\pm 5% or \pm 2mmHg (whichever is greater)	Identical
Pulse rate range	30 ... 250 bpm	30 ... 250 bpm	Identical
Pulse rate accuracy	\pm 5% or \pm 5 bpm, whichever is greater	\pm 5% or \pm 5 bpm, whichever is greater	Identical
Monitored Parameter: Temperature			
Temperature range	10 ... 45°C	10 ... 45°C	Identical
Accuracy	\pm 0.1°C	\pm 0.1°C	Identical
Measurement	Esophageal/Nasopharyngeal/Tympanic/Rectal/Bladder/Axillary/skin/Airway/Room/Myocardial/Core/Surface	Esophageal/Nasopharyngeal/Tympanic/Rectal/Bladder/Axillary/skin/Airway/Room/Myocardial/Core/Surface.	Identical
Measurement technique	Thermally sensitive resistor	Thermally sensitive resistor	Identical
Monitored Parameter: CO2			
Measurement Technique	S/5TM Single-width Airway Module, E-miniC (K052582).	S/5TM Single-width Airway Module, E-miniC (K052582).	Identical
Measurement	Side stream, FiCO2 and EtCO2 values, respiration rate (RR)	Side stream, FiCO2 and EtCO2 values, respiration rate (RR)	Identical
Monitored Parameter: Full Gas			

Measurement technique	Non-dispersive infrared absorption, paramagnetic differential oxygen measurement	Non-dispersive infrared absorption, paramagnetic differential oxygen measurement	Identical
Measurement Module Support	CARESCAPE Respiration module(K123195) (E-sCO ₂ ,E-sCAiO, and compatible with E-sCOV and E-sCAiOV but disabled spirometry function) Airway Gas Option (N-CAiO) Measurement parameter: C - EtCO ₂ , FiCO ₂ , and N ₂ O Ai - Anesthetic agents w/ identification and agent mixture detection O - FiO ₂ , EtO ₂ and FiO ₂ /EtO ₂ difference	CARESCAPE Respiration module(K123195) (E-sCO ₂ ,E-sCAiO, and compatible with E-sCOV and E-sCAiOV but disabled spirometry function) Airway Gas Option (N-CAiO) Measurement parameter: C - EtCO ₂ , FiCO ₂ , and N ₂ O Ai - Anesthetic agents w/ identification and agent mixture detection O - FiO ₂ , EtO ₂ and FiO ₂ /EtO ₂ difference	Identical
Monitored Parameter: Entropy			
Measurement	RE value, SE value, BSR value	RE value, SE value, BSR value	Identical
Measurement technique	Entropy monitoring is based on acquisition and processing of raw EEG and FEMG signals using the Entropy algorithm.	Entropy monitoring is based on acquisition and processing of raw EEG and FEMG signals using the Entropy algorithm.	Identical
Monitored Parameter: Non-Invasive Blood Pressure			
Measurement Technique	Oscillometric with step deflation	Oscillometric with step deflation	Identical
Algorithm Selection	SuperStat (DINAMAP) K022834	SuperStat (DINAMAP) K022834	Identical
Displayed Parameters	Systolic, diastolic, and mean pressures, auto cycle time and the time since the last determination(when manual mode) , and cuff/hose type, inflation cuff pressure(When measurement start)	Systolic, diastolic, and mean pressures, auto cycle time and the time since the last determination(when manual mode) , and cuff/hose type, inflation cuff pressure(When measurement start)	Identical
Measurement Ranges	Systolic: 30 to 290 mmHg (adult/pediatric) 30 to 140 mmHg (neonate) Map: 20 to 260 mmHg (adult/pediatric) 20 to 125 mmHg (neonate) Diastolic: 10 to 220 mmHg (adult/pediatric) 10 to 110 mmHg (neonate)	Systolic: 30 to 290 mmHg (adult/pediatric) 30 to 140 mmHg (neonate) Map: 20 to 260 mmHg (adult/pediatric) 20 to 125 mmHg (neonate) Diastolic: 10 to 220 mmHg (adult/pediatric) 10 to 110 mmHg (neonate)	Identical
Feature/Function	Current Device/System the legally marketed predicate Monitor B40V2.1 (K133576)	Proposed Device/System Name proposed Monitor B40i	Change Explanation/Notes
Monitored Parameter: Impedance Respiration on adult and pediatric patient populations			
Measurement Technique	Impedance variation detection. Excitation frequency 31.25 kHz	Impedance variation detection. Excitation frequency 31.25 kHz	Identical
Displayed Parameters	RESP rate	RESP rate	Identical
Measurement range	4 - 120 breaths/minute	4-120 breaths/minute	Identical
Measurement accuracy	+5% or +5 bpm, whichever is greater	+5% or +5 bpm, whichever is greater	Identical

Determination of Substantial Equivalence
(807.92(b)(1):

Summary of Non-Clinical Tests:

The CARESCAPE Monitor B40i and its applications comply with voluntary standards as detailed below. The following quality assurance measures were applied in the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final acceptance testing (Validation)
- Performance testing (Verification)
- Safety testing (Verification)

The CARESCAPE Monitor B40i was designed and tested for compliance to the following standards:

1. IEC 60601-1: 1988+A1: 1991+A2: 1995 Medical electrical equipment - Part 1: General requirements for safety
2. IEC60601-1-2: 2007 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
3. IEC60601-1-4: 2000 Medical electrical equipment - Part 1-4: General requirements for safety - Collateral Standard: Programmable electrical medical systems
4. IEC60601-1-8: 2006 Medical electrical equipment - Part 1-8: General requirements for safety - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
5. IEC 60601-2-27:2005- Medical Electrical Equipment-Part 2: Particular requirements for the safety of electrocardiographic monitoring equipment, except for the clause 50.102.8 a). Frequency response
6. IEC 60601-2-30:1999, Medical electrical equipment - Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment
7. IEC 60601-2-34:2000, Medical electrical equipment - Part 2-34: Particular requirements for the safety, including

essential performance, of invasive blood pressure monitoring equipment

8. IEC 60601-2-49:2001, Medical electrical equipment - Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment
9. AAMI / ANSI EC13:2002/(R)2007 Cardiac devices, heart rate meters, and alarms
10. AAMI SP10:2002+A1:2003+R:2008 +A2:2006 +R:2008 Manual, electronic, or automated sphygmomanometers
11. EN 12470-4:2000, A1:2009, Clinical Thermometers - Part 4: Performance of Electrical Thermometers for Continuous Measurement. Except for the clause 6.3 b) Temperature measurement error with single use probes exceeded maximum permissible error.
12. ISO 21647:2004 + C1:2005, Medical electrical equipment - Particular requirements for the basic safety and essential performance of respiratory gas monitors
13. ISO9919:2005, Medical electrical equipment Particular requirements for the safety and essential performance of pulse oximeter equipment for medical use
14. IEC 62304:2006, Medical devices - Medical device software - Software life cycle processes
15. IEC 60601-2-26:2002, Medical electrical equipment - Part 2-26: Particular requirements for the safety of electroencephalographs.
16. IEC 62366:2007, Medical devices - Application of usability engineering to medical devices

Clinical (807.92(b)(2)): Summary of Clinical Tests:

No additional clinical tests were performed for proposed monitor B40i

Conclusion (807.92(b)(3)): GE Healthcare considers the proposed monitor B40i to be as safe, as effective, and performance is substantially equivalent to the predicate devices.